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EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/12/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/526,582

Applicant(s)

FITZPATRICK ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 9/6/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/526,582 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Amendment Entry***

2. Applicant's amendment and response filed 5/29/02 in Paper No. 15 is acknowledged and has been entered. Claims 1, 5-7, 9-10, 16, 19, and 20-22 have been amended. Claim 23 has been cancelled. Accordingly, claims 1-22 are pending and are under examination.

### **Rejections Moot and Withdrawn**

3. The rejections of claim 23 under 35 U.S.C. 112 and 103, are hereby, withdrawn.

4. In light of Applicant's amendment and arguments, the rejections of claims 1-3 and 20 under 35 U.S.C. 102(b) as being anticipated by 1) Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) are hereby, withdrawn.

5. In light of Applicant's amendment and arguments, the rejection of claims 1, 2, and 4 under 35 U.S.C. 102(e) as being anticipated by Kundu et al. (US 6,210,906) is hereby, withdrawn.

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6. In light of Applicant's amendment and arguments, the rejection of claims 5-7, 10-14, and 16-18 under 35 U.S.C. 103(a) as being unpatentable over 1) Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fellman et al. (US 5,112,758) is hereby, withdrawn.

7. In light of Applicant's amendment and arguments, the rejection of claims 21-22 under 35 U.S.C. 103(a) as being unpatentable over 1) Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Schneider (US 6,291,178) is hereby, withdrawn.

**Rejections Maintained**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite, and incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

-In reciting, "a method of determining ... comprising reacting apolipoproteins in a saliva ... with antibodies ... using a quantitative assay kit comprising means for collection of saliva ..." it is unclear how the "means for collection of saliva" relate

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structurally and functionally to the “method for determining the level of an apolipoprotein in saliva” because there does not appear to be a method step of “collecting saliva”.

Claim 1 is vague, indefinite, and incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 fails to clearly define a detection step.

-In reciting, “detecting the amount of immunoreactivity between the antibodies and apolipoproteins as determined by the quantitative assay”, claim 1 fails to distinctly define that the recited “immunoreactivity” should be a detected to reflect a measure of the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive thereto; thus, a quantitative assay. Thereafter, the detected amount is correlated with known standards. See page 12-13 and 19 in the specification where Applicant provides performing a detection and quantitation of the antibody bound to apolipoprotein in order to determine the level of immunoreactivity of apolipoprotein in saliva by correlating the result to known standards.

Claim 2 is vague and indefinite in reciting, “components thereof” because it is unclear as recited what is encompassed by the term “components thereof” and how they related and differ, i.e. in reactivity or binding capability, from the complete form of apolipoprotein, i.e. ApoA, ApoB, etc.

Claim 10 is vague and indefinite in reciting, “collecting the saliva into a device which filters out mucopolysaccharides and comprises the antibodies immunoreactive with ... apolipoproteins” because it is unclear how this instant device relates to the quantitative assay kit in claim 1 from which it depends. As recited, two separate

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elements or components are being used separately with separate purposes, which does not appear to be Applicant's intent.

Claim 12 has improper antecedent basis problem in reciting, "the levels in serum".

Claim 14 is vague and indefinite in reciting, "components thereof" because it is unclear as recited what is encompassed by the term "components thereof" and how they related and differ, i.e. in reactivity or binding capability, from the complete form of apolipoprotein, i.e. ApoA, ApoB, etc.

Claim 19 is vague and indefinite in reciting, "as separate reagents, antibodies to" because it is unclear how this instant reagent in claim 19 relates to the "reagents for detection" recited in claim 17 which is further comprised in the kit or device.

Claim 20 is vague, indefinite, and incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 fails to clearly define a detection step.

-In reciting, "determining the amount of immunoreaction between the antibodies and the apolipoproteins in the saliva sample", claim 1 fails to distinctly define that the recited "immunoreaction" should be detected to reflect a measure of the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive thereto. Thereafter, the detected amount is correlated and compared to with known standards. See page 12-13 and 19 in the specification where Applicant provides performing a detection and quantitation of the antibody bound to apolipoprotein

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in order to determine the level of immunoreactivity of apolipoprotein in saliva by correlating the result to known standards.

Claim 20 is vague and indefinite in reciting, "components thereof" because it is unclear as recited what is encompassed by the term "components thereof" and how they related and differ, i.e. in reactivity or binding capability, from the complete form of apolipoprotein, i.e. ApoA, ApoB, etc.

Claim 20 step c) has improper antecedent basis problems in reciting, "the antibodies immunoreactive with the apolipoprotein in the saliva sample with known quantities of". Perhaps, Applicant intends starting from line 2, "immunoreactivity of antibodies immunoreactive with apolipoproteins in saliva of normal or at risk individuals having known quantities of apolipoproteins".

Claim 20 is vague, indefinite, and incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, the preamble requires 1) quantitating the amount of lipoprotein or cholesterol in saliva, or 2) determining the presence of lipid disorders or risk of cardiovascular disease; however none of the method steps recite 1) reacting either one of lipoprotein or cholesterol in saliva with antibodies specific thereto, 2) detecting complexes formed between the lipoprotein or cholesterol with antibodies specific thereto so as to obtain a quantitation of the amount of lipoprotein or cholesterol, and 3) correlating the detected amounts with the presence of lipid disorders or risk of cardiovascular disease.

Claim 21 lacks antecedent support in reciting, "the levels of HDL and/or LDL in the serum" and "the levels of apolipoproteins in serum."

Claim 21 is indefinite in reciting, "HDL and LDL". Acronyms or abbreviations must be recited at least one time in a set of claims.

Regarding claim 21, "and/or " renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and/or "), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

In claim 21, it is unclear what functional relationship exists between "HDL and LDL in serum and apolipoproteins in serum" and the elements recited in claim 20 from which it depends so as to be able to establish a correlation step between the elements.

Claim 22 is vague and indefinite in reciting, "components thereof" because it is unclear as recited what is encompassed by the term "components thereof" and how they related and differ, i.e. in reactivity or binding capability, from the complete form of apolipoprotein, i.e. ApoA, ApoB, etc.

Claim 22 is confusing in reciting, "apolipoprotein in serum known to be correlated to the presence of lipid disorders or risk of cardiovascular disease in the patient". Perhaps Applicant intends, "known apolipoprotein levels from serum samples of patients having lipid disorders or risk of cardiovascular disease". Please clarify.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 5-7, 10-14, 16-18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fellman et al. (US 5,112,758) and in further view of Schneider (US 6,291,178).

Oberhardt discloses an immunoassay for detection of apolipoproteins such as apo-A1 and apo B-100 on difficult biological samples such as saliva (see column 3, lines 24-31 and column 4, lines 11-16). Specifically, Oberhardt discloses reacting the sample with a dry reagent containing antibodies immunoreactive to the apolipoproteins, binding the apolipoproteins (analyte) to a reaction cascade initiator and magnetic particles; thus, forming a reaction mixture (see column 5, lines 47-64). Thereafter, Oberhardt discloses applying oscillating or moving static magnetic field to the reaction mixture to activate the reaction cascade initiator, monitoring the response of the magnetic particles to provide a signal, then determining the concentration of the

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apolipoprotein based on the signal (see also column 14, line 50 bridging to column 15, line 44). Depending on the assay, other reagent components may be included and used with the dry reagent such as buffers and neutralizers (see column 6, lines 39-44). The immunoassay is performed on a strip or dipstick (reaction slide) (see column 6, lines 4-29). Oberhardt discloses application of the invention to a panel of affinity assays or immunoassays for different but related analytes in single application of the sample to the reaction slide by utilizing different reaction elements and reagent components (see column 4, lines 34-43). Depending on the assay, the dry reagent and all reagent components including buffers and neutralizers may be incorporated into a kit format (see claims 34-37).

Oberhardt or Oberhardt differ in failing to disclose a means for collecting saliva.

Fellman et al. disclose a method and kit for stimulating saliva production (inducing salivation) in a subject using a sour stick (ascorbic acid) (see column 3, lines 45-61). Fellman et al. also teach treating saliva prior to diagnostic testing using cationic quaternary ammonium reagents. Specifically, Fellman et al. disclose that centrifuge and filters are known techniques for removing mucopolysaccharides from saliva. According to Fellman et al., viscosity reduction is necessary for the preparation of body fluids containing mucopolysaccharides for accuracy in testing, i.e. detecting for presence of antibodies and antigen (see column 1 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Fellman in removing mucopolysaccharides to reduce viscosity of a specimen into the method and kit taught

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by 1) Oberhardt and 2) Oberhardt in detecting apolipoproteins in the saliva because Fellman specifically taught that removal of this excess element decreases background noise which prevents useful and accurate detection of analyte such as the apolipoproteins (see Fellman et al., column 3, lines 15-25).

1) Oberhardt, 2) Oberhardt, and Fellman et al. differ from the instant invention in failing to teach correlating lipoprotein levels between serum sample and the saliva.

Schneider discloses a method and apparatus for collecting saliva for use in assaying for the presence of biologics such as lipoproteins and cholesterol. According to Schneider, analytes such as lipoproteins, cholesterol, including (blood) alcohol, which are present in the blood plasma are also found to be present in the saliva. Schneider also discloses that correlations between saliva and blood plasma levels are deduced using known protocols in the art, i.e. A. W. Jones, Clin. Chem. (1993) Vol. 39(9): 1837-1843 (see column 2, line 45 to column 3, line 11 and also column 4, lines 24-65).

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Schneider in correlating saliva levels of lipoprotein and cholesterol with their levels in the blood, into the method taught by the Oberhardt patents and modified by Fellman, in determining apolipoprotein levels because Schneider specifically taught that knowledge of correlative equivalence of analyte values in saliva in relation to blood levels provides the advantage of utilizing non-invasive procedure in determining analyte concentration in a patient by collecting saliva rather than drawing blood from the patient.

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10. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kundu et al. (US 6,210,906) in view of Fellman et al. (US 5,112,758) and in further view of Schneider (US 6,291,178).

Kundu et al. disclose detecting apolipoprotein A in a saliva sample using labeled monoclonal antibodies against kringle 5 domain of apolipoprotein A (see Abstract, column 4, lines 39-52, and column 8, lines 8-15). Kundu et al. disclose labeling the antibodies using chromogen, fluorescent compounds, radioactive labels, etc. (see column 9, lines 57-67).

Kundu et al. differ from the instant invention in failing to disclose a means for collecting saliva.

Fellman et al. disclose a method and kit for stimulating saliva production (inducing salivation) in a subject using a sour stick (ascorbic acid) (see column 3, lines 45-61). Fellman et al. also teach treating saliva prior to diagnostic testing using cationic quaternary ammonium reagents. Specifically, Fellman et al. disclose that centrifuge and filters are known techniques for removing mucopolysaccharides from saliva. According to Fellman et al., viscosity reduction is necessary for the preparation of body fluids containing mucopolysaccharides for accuracy in testing, i.e. detecting for presence of antibodies and antigen (see column 1 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Fellman in removing mucopolysaccharides to reduce viscosity of a specimen into the method and kit taught by Kundu in detecting apolipoproteins in the saliva because Fellman specifically taught

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that removal of this excess element decreases background noise which prevents useful and accurate detection of analyte such as the apolipoproteins (see Fellman et al., column 3, lines 15-25).

Kundu et al. and Fellman et al. differ from the instant invention in failing to teach correlating lipoprotein levels between serum sample and the saliva.

Schneider discloses a method and apparatus for collecting saliva for use in assaying for the presence of biologics such as lipoproteins and cholesterol. According to Schneider, biologics such as lipoproteins, cholesterol, including (blood) alcohol, which are present in the blood plasma are also found to be present in the saliva. Schneider also discloses that correlations between saliva and blood plasma levels are deduced using known protocols in the art, i.e. A. W. Jones, Clin. Chem. (1993) Vol. 39(9): 1837-1843 (see column 2, line 45 to column 3, line 11 and also column 4, lines 24-65).

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Schneider in correlating saliva levels of lipoprotein and cholesterol with their levels in the blood, into the method taught by the Kundu and modified by Fellman, in determining apolipoprotein levels because Schneider specifically taught that knowledge of correlative equivalence of analyte values in saliva in relation to blood levels provides the advantage of utilizing non-invasive procedure in determining analyte concentration in a patient by collecting saliva rather than drawing blood from the patient.

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11. Claims 8-9, 15, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fellman et al. (US 5,112,758) and in further view of Schneider (US 6,291,178) as applied to claims 1-3, 5-7, 10-14, 16-18, and 20-22 above, and further in view of Fisher et al. (Diabetes Research and Clinical Practice, 1991) and Coppo et al. (Journal of Diabetic Complications, 1987).

1) Oberhardt or 2) Oberhardt, Fellman et al., and Schneider have been discussed supra.

1) Oberhardt or 2) Oberhardt, Fellman et al., and Schneider differ from the instant invention in failing to teach means for determining the amount of albumin in the saliva and means for normalizing the amount of apolipoprotein to the amount of albumin present in the saliva and antibodies immunoreactive to albumin in the device or kit for determining apolipoprotein concentration.

Specifically, Fisher et al. teach using citric acid to stimulate saliva secretion then measuring its albumin level using ELISA kit and method. Fisher et al. compare albumin concentration between saliva and urine in diabetes patients.

Coppo et al. teach determining urinary albumin concentrations using anti-albumin antibody in an indirect ELISA kit and technique.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Coppo in using anti-albumin antibodies to measure the level of albumin in a body fluid such as urine using ELISA technique or saliva such as in the ELISA method taught by Fisher, into the method and device taught

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by 1) Oberhardt or 2) Oberhardt as modified by Fellman and Schneider because 1) Oberhardt and 2) Oberhardt specifically suggested application of their kit and method in multianalyte or panel screening applications for any antigen combination present in body fluids, such as apolipoproteins and albumin present in saliva, using respective immunoreactive antibodies that are specific thereto. Further, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the reagents, labels and immunoreactive antibodies specific for albumin in the method taught by Coppo into a kit arrangement because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

It further would have been prima facie obvious to one of ordinary skill in the art to perform statistical evaluation of concentration levels between coexisting analytes present in a body fluid and effect correction, if necessary, to remove effects of possible interference or dilution, so that an actual concentration of the desired analyte is obtained since statistical correction methods are standard in laboratory practice during optimization procedures.

### ***Response to Arguments***

12. Applicant's arguments with respect to previous rejections have been considered but are moot in view of the new ground of rejection.

13. Applicant's arguments filed 5/29/02 have also been fully considered but they are not persuasive.

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A) Applicant argues that the Oberhardt patents do not suggest the detection of apolipoprotein levels in saliva.

In response, the Oberhardt patents indeed, suggest detecting apolipoproteins levels in saliva in column 4, lines 11-16 using immunoreactive antibodies and detecting a response or a signal from the reaction mixture.

B) Applicant argues that the Oberhardt patents do not suggest that there is a correlation between levels in the saliva and the blood. Applicant argues that neither of the Oberhardt patents teach detecting levels in saliva and then extrapolating, therefrom, the serum concentration.

In response to applicant's argument that both Oberhardt patents do not suggest correlating the levels of apolipoprotein in the saliva with the levels in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claim 1 only recites, "comparing ... with standards of known amounts of apolipoproteins reacted with the antibodies", claim 12 only recites, "means for comparing ... apolipoproteins in the saliva with the levels in serum", and claim 20 only recites, "comparing ... with known amount quantities of apolipoprotein in normal or at risk individuals". Contrary to Applicant's arguments, there is no requirement in the rejected claims that the known standards are blood/serum levels, there is no indication based on the recited claims that there is a direct correlation between saliva concentrations of



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apolipoproteins and serum concentrations of apolipoproteins, and there is no indication that saliva results can be used to extrapolate serum apolipoprotein levels.

C) Applicant argues that the Kundu does not suggest the detection of apolipoprotein levels in saliva.

Indeed, Kundu discloses detecting apolipoprotein A in a saliva sample by immunoreacting labeled monoclonal antibodies with the Apo A in the sample, specifically against kringle 5 domain of apo A.

D) Applicant argues that the Kundu does not suggest detecting levels in saliva and then extrapolating, therefrom, the serum concentration.

In response to applicant's argument that Kundu does not suggest correlating the levels of apolipoprotein in the saliva with the levels in blood, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claim 1 only recites, "comparing ... with standards of known amounts of apolipoproteins reacted with the antibodies", claim 12 only recites, "means for comparing ... apolipoproteins in the saliva with the levels in serum", and claim 20 only recites, "comparing ... with known amount quantities of apolipoprotein in normal or at risk individuals". Contrary to Applicant's arguments, there is no requirement in the rejected claims that the known standards are blood/serum levels, there is no indication based on the recited claims that

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there is a direct correlation between saliva concentrations of apolipoproteins and serum concentrations of apolipoproteins, and there is no indication that saliva results can be used to extrapolate serum apolipoprotein levels.

14. For reasons aforementioned, no claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel  
November 4, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641